

REMARKS

Careful consideration has been given by the applicant to the Examiner's comments and rejection of the claims, as set forth in the outstanding Office Action, and favorable reconsideration and allowance of the application, as amended, is earnestly solicited.

Applicant notes the Examiner's objections to the arrangement of the specification and appropriate section headings and corrections, as required by the Examiner, with regard to minor typographical errors, have also been incorporated therein, thereby fully meeting the Examiner's objections concerning the specification.

In this connection, amended drawings are being submitted in conjunction with an additional corrected reference numeral "12" to obviate the objection concerning the w's of the reference numeral "10" in the disclosure. The foregoing should fully meet all of the formal requirements concerning the specification, drawings and abstract.

Applicants further note the rejection of the claims under 35 U.S.C. §101 referring to the "femur" in positive terminology in the claims. The newly presented claims, Claims 7-14, which replace cancelled Claims 1-6, have taken cognizance of this particular formality in drafting the terminology.

Furthermore, applicant notes the numerous objections and grounds of rejection under 35 U.S.C. §112, with regard to Claims 1-5, and the newly presented claims have fully taken cognizance of the Examiner's suggestions pertaining to terminology.

Furthermore, applicant also notes the rejection of Claim 6 as being improperly dependent, and the rejection of Claims 1-5 under 35 U.S.C. §102(b), as being allegedly anticipated by Walker, U.S. Patent No. 5,330,533, as extensively discussed in the Office Action.

Accordingly, in order to clearly and unambiguously define patentable subject matter in view of the prior art, as represented by Walker, applicant has cancelled Claims 1-6 without prejudice and in lieu thereof herewith presents new Claims 7-14, which are deemed to define the inventive features of the present case in clear terminology distinguishing over Walker.

In particular, the subject matter of original Claim 4 has now been incorporated into new Claim 7, so as to further define the configuration of the knee prosthesis, which patentably distinguishes over the prior art and which defines a unique and inventive concept, not at all known in the current technology, as also extensively discussed in the present specification.

In particular, reverting to the prior art, as represented by the prosthesis, it is the object of the knee prosthesis to provide a specific three-dimensional configuration of a femoral component and a particular shape of a plastic component or insert, which is designed to obtain a unique three-dimensional shape of the prosthesis; the facility of obtaining three-dimensional movements and three-dimensional kinematics of the femoral component on the insert; and to obtain three-dimensional contacts between the femoral component and the insert during all movements of the femur on the plastic insert, thereby obtaining significant advantages in the reduction in wear and in the quality of the functioning; in effect, comfort to the patient during

all movements of the operated knee of the patient by means of the present inventive prosthesis.

Consequently, applicant notes that it is important to provide a clear understanding of any differences in the three-dimensional configuration of one or both components of the inventive prosthesis, which will produce different patterns in the wear and kinematics when implanted in a patient's knee joint. Consequently, the difference in a single plane of one or more of the femur and the insert will produce different patterns of mobility, a degree of wear and of kinematics and must be considered as resulting in a different prosthesis from that described in Walker or any other references in the prior art.

In essence, notwithstanding some partial resembling aspects of components of the frontal plane, for example Figure 7c of Walker corresponds to section A-A of Figure 7a thereof, the inventive prosthesis is completely different from Walker, the latter of which is of the same general type as another Walker prosthesis referred to in the present specification under U.S. Patent No. 5,609,639, representative of the prior art.

In accordance with the Examiner's position, Walker discloses a knee prosthesis comprising a plurality of components such as:

1. a metal femoral component;
2. a metal tibial component and a plastic intermediate component;
3. two lateral condylar surfaces;
4. and a hollowed central part;

5. together with an intermediate component;
6. having two lateral cavities;
7. and a projecting central part.

These foregoing components 1-7 are general features, which are common to all known prosthesis for a period of over three (3) decades. In effect, these particular features or components are of basic technological background, which are common to Walker, the present knee prosthesis, and other prior art prosthesis and whereby the present invention clearly distinguishes there over.

Furthermore, pursuant to the Office Action, as defined by the Examiner, the prosthesis of Walker also comprises the following additional features:

8. the projecting central part of the intermediate component is convex in a frontal plane and concave in a sagittal plane – this is not an original feature, since it can be found in many recent new prosthesis.
9. the prosthesis of Walker does not exhibit sharp edges or a discontinuity – this is not correct, since Figure 4b of the Walker reference shows flat surfaces connected along angular lines or discontinuities to curved surfaces on the plastic intermediate component.
10. Walker shows the components having an undulating curve in the frontal plane (Fig. 4a, 4b, 7c) – this is not exact, since Figure 7c is an undulating curve only along the section line A-A of Figure 7a; if one looks forward or backward of line

A-A, one can see on Figure 4b that the surface 43 shows broken lines and angles in the direction of the femoral surface; on the contrary, in the prosthesis pursuant to the present invention, the frontal aspect is an undulating line form extending the front part to the rear part of the entire plastic insert and the entire femoral component.

11. Walker discloses the projecting central portion of the intermediate component as having a constant radius from front to rear. Concerning this essential point, applicant respectfully submits that there is a misunderstanding by the Examiner, pertaining to which an explanation is in order; as follows:

Reverting, in particular, to the Walker prosthesis, there is provided a constant radius of the condylar portion and of the intermediate component in the sagittal plane, referring to Figures 4A and column 1, lines 36-39.

However, a constant radius in a sagittal plane indicates that it is not a spiral provided for in that plane, unlike the present invention.

Walker primarily discloses that the tibial bearing surface provides for a radius of curvature which substantially corresponds to the radius of the femoral component, referring to column 1, lines 49-52, in effect, twice a constant radius which defines two cylindrical parts, one moving within the other.

Furthermore, according to Walker, as described in column 6, lines 50-54, the femoral condylar surfaces are intended to provide for a constant sagittal radius in the region which articulates against the plastic surface, and which conformed closely with the tibial surface on

both frontal and sagittal planes, whereby in that instance, the conformity is that of cylinder within a cylinder and does not define a spiral with another spiral.

In contrast with Walker, the present invention defines a prosthesis in which the intermediate component has a constant radius from front to rear when viewed in a frontal plane, however the radius in the sagittal plane is a spiral.

Thus, pursuant to the present invention, the radius of the condyles in the sagittal plane is also a spiral, wherein both the spirals are different but related to each other, as described on page 15 of the present specification.

The important distinctions between the inventive prosthesis, as provided and claimed herein, and the one described in Walker, is of an essential nature and there must be made reference in conjunction therewith concerning various disclosure portions in the Walker publication as follows:

1. Col. 1, lines 35-48: “the femoral component having a constant sagittal radius”;
2. Col. 1, lines 49-50: “the tibial bearing surface has a radius of curvature...corresponds with the radius of the surface” of the femoral component, i.e. constant;
3. Col. 1, lines 56-59: for the required laxity in the joint....the radii of the femoral sagittal sections may be slightly smaller than the radii of the corresponding sections of the tibial bearing surface;
4. Col. 1, line 68 to Col. 2, line 2: as in the application,...”the femoral component may be continued in the distal/posterior region across the full width,...the lateral

medial direction”, but the difference appears at Col. 2, lines 3-4: “the constant radius of the femoral component in the sagittal planes...”

5. Col. 2, line 43: “the cylindrical bearing surface between the plastics component and the metal platform”.
6. Col. 4, lines 48-51: Figure 3b...”the femoral shape is then used to computer generate a tibial surface 35 based on input laxity requirements in ant-post displacement and internal-external rotation”. This means that the surface of the insert is hollowed out by the antero-posterior and rotational movement of the femoral cylindrical surface (of a constant radius) and this cannot provide a spiral surface. Col. 4, lines 67-68: “Now there is a constant radius R for contacting the tibial surface 43”;
7. Refer to Claim 1: Col. 7, lines 54-57; femoral component.....wherein the radius constant from a posterior to a point more anterior to the distalmost point...
8. Claim 4: Col. 8, lines 24-26:...”wherein said cylinder has a radius which is at least as large”....

In summation, applicant notes that two important and patentable distinctions are clearly evident in view of the prior art, as represented by Walker. In essence, in contrast with Figure 4b of Walker, U.S. Patent No. 5,330,533, wherein there are disclosed flats and sharp edges, which would lead to difficulties for a patient during rapid movement and potentially malfunctioning of the prosthesis, in the present instance, there is a continuity and a complete elimination of any flats, edges or discontinuities across the entire extent of the undulating

curve of the prosthesis. This provides a clear advantage to a patient being provided with the inventive prosthesis.

Furthermore, a second important feature is the provision of the spiral shape of the femoral component and of the insert, whereby the movements of these two components relative to each other provide for an improved similarity to those of a normal knee of a patient.

Consequently, during knee joint flexion, due to the spiral shapes of the femoral component of the insert, there is a posterior displacement of the contact point between these two components, but no posterior movement of the femur on the insert, in effect the femoral bone is always at the same position above the tibial bone, irrespective of the knee angle of flexion.

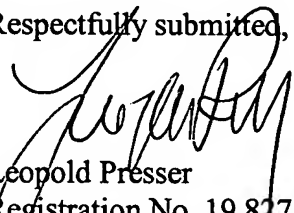
Based on the foregoing, it becomes, thus, clearly apparent that the disclosure of Walker provides limitations of a serious nature in his prosthesis, which are significantly different from the structure and functioning of the present knee prosthesis.

Accordingly, in order to clearly emphasize the foregoing distinctions, applicant has provided a new set of claims, which provide for a clarification in the different configuration and function relative to the prosthesis of Walker, and wherein these distinctions are deemed to be directed to clearly allowable and patentable claims, in view of which the early issuance of the Notice of Allowance is earnestly solicited.

Furthermore, applicant also requests that he be extended the courtesy of a personal or telephone interview with the Examiner in view of the important medical advance and commercial importance represented by the present invention.

In the event that the Examiner has any queries concerning the instantly submitted Amendment, these can be readily discussed in an interview, which will also be attended to by applicant's attorney and the inventor, Dr. Bercovy.

Respectfully submitted,



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